K002795

DEC - 6 2000

EXHIBIT 2

HyperTec Inc.
301 E. Main Street
Olney, TX 76374
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Contact: Travis Fromme, President
September 6, 2000

510(k) Summary of Safety and Effectiveness

1. Identification of the Device:
   Proprietary-Trade Name: "Model Hybrid 3200 Monoplace" Hyperbaric Therapy Systems.
   Classification Name: Hyperbaric Chamber 73CBF
   Common/Usual Name: Hyberbaric Chamber

2. Equivalent legally marketed device: This product is similar in design and identical in function to the Perry Baromedical Perry Baromedical SIGMA Plus I Monoplace, K974868/K832127

3. Indications for Use (intended use) The following indications are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee of the Undersea and Hyperbaric Medical Society (UHMS). The UHMS is the primary source of information for diving and hyperbaric medicine physiology worldwide.

- Air or Gas Embolism
- Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
- Clostridal Myositis and Myonecrosis (Gas Gangrene)
- Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias
- Decompression Sickness
- Enhancement of Healing in Selected Problem Wounds
- Exceptional Blood Loss (Anemia)
- Intracranial Abscess
- Necrotizing Soft Tissue Infections
- Osteomyelitis (Refractory)
- Delayed Radiation Injury (Soft Tissue and Bony Necrosis)
- Skin Grafts & Flaps (Compromised)
- Thermal Burns

4. Description of the Device: The HyperTec Hybrid 3200 Monoplace Hyperbaric System is designed and constructed to the requirements of ASME Boiler and Pressure Code, Section VIII, Division 1. The standards stipulated in ASME PVH0-1c-1996, Safety Standard for Pressure Vessels for Human Occupancy, and NFPA 99

requirements concerning hyperbaric facilities have been adhered to. The HyperTec Hybrid 3200 Monoplace Hyperbaric System has been designed for safe, easy operation and maintenance. It consists of a pressure vessel and control system; both mounted on a chassis. The chamber pressure vessel is comprised of a carbon steel cylinder with an end head, a quick opening door, and a transparent acrylic cylinder. The control console is located on the steel hull section, where it is readily accessible. All chamber components are designed for ease of operation and require minimum maintenance. The chamber is pressurized with customer supplied, pure medical grade oxygen. During treatment, the patient breathes directly from the chamber atmosphere, and does not require any additional breathing apparatus, such as a breathing mask or hood. A sliding stretcher is provided to facilitate patient entrance and exit of the HBOT system. The system provides many features for both the patient and operator..

5. Safety and Effectiveness, comparison to predicate device:

Comparison Areas	Perry Baromedical SIGMA Plus I Monoplace, K974868/K832127.	HyperTec Model Hybrid 3200 Monoplace
Indications for use	Air or Gas Embolism Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning Clostridal Myositis and Myonecrosis (Gas Gangrene) Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias Decompression Sickness Enhancement of Healing in Selected Problem Wounds Exceptional Blood Loss (Anemia) Intracranial Abscess Necrotizing Soft Tissue Infections Osteomyelitis (Refractory) Delayed Radiation Injury (Soft Tissue and Bony Necrosis) Skin Grafts & Flaps (Compromised) Thermal Burns"	SAME
Design Codes & Standards	ASME Sec VIII Div. 1, PVHO-1, NFPA 99 & 70, UL 2610,	SAME
Materials	ASME Boiler & Pressure Vessel Code, Section II	Approved materials as listed in PVHO-1-1997 Section 1.3, 3, & 4, NFPA 99.
Number of Patients	ONE	SAME
Physical Characteristics	Internal volume – 26.5 cu. Ft. Internal Diameter 25 ¼" Weight - 1200 lbs.	Internal volume - 26 cu. Ft. Overall length 82", width 39", height 48" Internal Diameter 32" Weight – 2500 lbs.
Performance		
Max. operating pressure	30 psig/3 ATA	SAME
Max. pressurization rate	1-5 psig/minute	SAME

Emergency de-pressurization rate	.65 psig/sec	SAME
Ventilation rate	150-385 liters/min	150-400 liters/min
Operating Temp.	32 – 120 Degrees F	20 – 120 Degrees F
Energy required	115 VAC	SAME
Human Factors	Patients are supine only, acrylic tube helps with patient claustrophobia	SAME
Anatomical sites	Entire body	SAME
Compatibility with other devices	IV and telemetry connections in the shell are compatible with industry standard devices.	SAME
Where used	Hospitals & Clinics	SAME

6. Conclusion

In all respects, the "Model Hybrid 3200 Monoplace" Hyperbaric Therapy Systems are substantially equivalent to one or more clinical monoplace hyperbaric chambers that are legally marketed for the conduct of hyperbaric oxygen therapy. Testing and certifications demonstrate that the device meets the standards referenced above.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC - 6 2000

Mr. Daniel Kamm
HyperTec, Inc.
c/o Kamm & Associates
P.O. Box 7007
Deerfield, IL 60015

Re: K002795
"Model Hybrid 3200 Mnoplace" Hyperbaric Therapy Systems
Regulatory Class: II (two)
Product Code: 73 CBF
Dated: September 5, 2000
Received: September 7, 2000

Dear Mr. Kamm:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4648. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597, or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

j) Indications for Use

510(k) Number K002795

Device Name: HyperTec "Model Hybrid 3200 Monoplace" Hyperbaric Therapy System.
Indications for Use: All of the contemporary substantially equivalent systems listed as predicate devices are used for the same indications as listed in the Hyperbaric Oxygen Therapy: Committee Report, Undersea and Hyperbaric Medical Society, Inc., Revised 1999:

"The following indications are approved uses of hyperbaric oxygen therapy as defined by the Hyperbaric Oxygen Therapy Committee.

- Air or Gas Embolism
- Carbon Monoxide Poisoning or Carbon Monoxide Poisoning Complicated by Cyanide Poisoning
- Clostridal Myositis and Myonecrosis (Gas Gangrene)
- Crush Injury, Compartment Syndrome, and other Acute Traumatic Ischemias
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- Thermal Burns"

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Cardiovascular & Respiratory Devices
510(k) Number K002795

Prescription Use X OR Over the Counter Use_____
(Per 21 CFR 801.109)